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Kathryn M. Kosh 28 October 1995
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V. INTRODUCTION

a. Nature of the problem.

With the increased media attention focused on the importance of the early detection of breast cancer, more women were beginning to recognize the need for breast cancer screening and to look for places (programs, clinics, doctors) where they could obtain quality breast care. As women learn about their family history of breast cancer, they begin to speculate about their own risk. In addition, many women have heard that there is a gene (BRCA1) responsible for a small portion of breast cancer cases that was cloned last year. Already these women are requesting genetic testing as soon as it is available on a clinical level. We need to think about the psychological consequences for these women, as well as the ethical implications. Without adequate information, many women overestimate their risk and become quite fearful that they too could develop breast cancer. Our previous study identified anxiety as predictive of poor adherence to both clinical breast examinations and breast self-examination, as well as delay in having a mammogram (Kash et al, 1992). Thus adherence to breast cancer screening poses a major problem for women at increased risk who need timely screening. The emotional distress may also diminish a woman's quality of life, if the fear of developing breast cancer interferes with goal directed behaviors and problem solving activities. This information compelled us to intercede with women at increased risk for breast cancer and develop an intervention that could help to improve quality of life and increase adherence to breast cancer screening. Since women at increased risk increasingly identify themselves and look for programs where they can not only find out appropriate surveillance guidelines but share their feelings and concerns with others, the efficacy of a group intervention needed to be tested in a controlled trial. This study was designed to examine the role of such an intervention in improving quality of life and increasing adherence to screening behaviors (mammogram, breast self-examination, clinical breast examination). Our previous work, described below, piloted this intervention and found it to be extremely helpful to women in decreasing risk perception and increasing adherence to screening.

b. Background of previous work

Prior to the grant proposal, we conducted preliminary work on piloting a group psychoeducational intervention. There were three important components to this six week, structured intervention. The first was educating women: a) providing their objective risk status by giving them their own family tree (pedigree), b) clarifying information about breast cancer and risk factors for breast cancer; c) providing information on ways to take control of their lifestyle by changing their eating patterns; d) instructions on breast self-examination using both active and passive methods; and e) reinforcing the importance of adherence to screening guidelines. The second component revolved around cognitive restructuring, which helps to facilitate problem-solving. That is, we encouraged women to use active coping rather than avoidance or denial in dealing with their risk status. In addition, changing cognitions can help to alleviate anxiety and the sense of helplessness. The last component was that of emotional support which helped: a) to decrease the sense of isolation; b) to encourage sharing feelings and thoughts with others; and c) to provide reassurance by and rapport with other women.

In the pilot group ten women were randomly chosen from a group of 100 who responded affirmatively to participating in a group. These ten women completed baseline and six-week assessments. Perceived susceptibility for developing breast cancer significantly decreased ($p < .02$) on paired t-tests during the six weeks and approximated their actual risk, based on risk analysis tables. All of the women reported that their knowledge of breast cancer increased and

misconceptions were clarified. Anxiety and fears about developing breast cancer and its consequences were diminished in 90% of these women. Thirty percent who had never performed BSE began to do so and expressed their intent to perform it monthly. Women felt that the emotional support provided by the group was extremely important, as well as was the opportunity to exchange feelings and information with women facing the same problems who coped with them daily, using a range of strategies. At a two month follow-up session, all women reported performing monthly BSE. At six months, one year, two years, and three years, there was 90% adherence to mammogram schedule and CBE; 100% were performing BSE monthly. Seventy-five percent of women also reported using the information from the dietician to reduce their fat intake (Kash, 1991).

Using the information from the above mentioned pilot group, we refined our intervention and developed a structured format for the group leader and session leaders to follow. We collected baseline data via a telephone questionnaire on 20 women and randomized them to either the intervention or control group. Analyses of variances on baseline data revealed no significant differences between the groups on any of the demographic, independent, or outcome variables. Within this model our goals were; to provide women with accurate and clear information on actual risk status, breast cancer, risk factors, methods of risk reduction (e.g., low fat diet), appropriate surveillance procedures; and help women learn how to actively cope with their risk. The group then met for six consecutive weeks. The structure and content of these sessions was similar to that of the pilot group and is described in the manual below.

At the end of the six week group intervention telephone assessments were conducted by a trained interviewer. The interviewer was blind as to which group the woman belonged. Within the intervention group there was a significant increase in knowledge ($p < .05$), a significant decrease in perceived risk or susceptibility ($p < .015$), and a significant decrease in perceived barriers to screening ($p < .05$) between baseline and six weeks (the end of the group). Analyses of variances at Time 2 revealed several changes between the groups: 1) a significant increase ($p < .005$) on knowledge of breast cancer in the experimental group; 2) a significant decrease ($p < .02$) on perceived barriers in the experimental group; and 3) a significant increase ($p < .03$) on knowledge of the risk factors for breast cancer in the experimental group. For example, at Time 2 there were still women in the control group (30%) who thought that being "hit in the breast" increased your chances of developing breast cancer. There were also significant differences between the two groups on perception of risk ($p < .001$) with only the experimental group accurately reporting their risk status. There were no difference between the groups on tension or depression at the end of six weeks. Our preliminary data was reported earlier this year (Kash et al, 1995).

c. Purpose of the present work

The purpose of this study is to address quality of life and adherence to screening issues associated with being at increased risk for breast cancer. The specific aims are: 1) to examine the impact of a psychoeducational intervention on the intermediate outcome variables of knowledge of breast cancer and risk factors, breast cancer beliefs, cancer attitudes, and coping skills in women at increased risk for breast cancer; 2) to examine the impact of a psychoeducational intervention on the endpoint variables of quality of life and adherence to screening in women at increased risk for breast cancer; and 3) to explore the mechanisms by which the psychological intervention may improve quality of life and increase adherence to breast cancer screening in women at increased risk for breast cancer.

d. Methods of approach

The research design uses a randomized controlled trial to test the psychoeducational group intervention. The intervention components (as identified above) include; social support enhancement, education, cognitive restructuring, and problem-solving. A total sample size of 360 is sufficient to allow hypotheses testing. Data will be collected at four points in time; baseline, six weeks, six months, and one year. The variables to be examined are: demographic; risk status; selection method; stressful life events; knowledge of breast cancer and risk factors; breast cancer beliefs; cancer attitudes; coping strategies; quality of life (psychological distress, role, work and family functioning, life satisfaction, satisfaction with health care, and participant goal-directed behaviors); and adherence to CBE, mammogram, and BSE. Preliminary analyses include descriptive statistics, correlational, and principal components analysis. Multivariate analysis of variance with repeated measures and appropriate covariates will be used to test the hypotheses.

VI. PROGRESS REPORT

a. Experimental methods used

The medical history for all women enrolled in the Strang Breast Surveillance Program are reviewed by Dr. Kash (PI) for eligibility to participate in the study. Names of eligible women are randomly selected. Those women selected were sent a letter explaining the purpose and requirements of the study. Each woman who does not respond within a two week period were contacted by telephone by Ms. Hernandez (Research Assistant) and told of the study project and exactly what is being asked of them. It was explained to each woman that after baseline data was obtained they would be randomized to either the experimental (standard care plus an intervention group) or the control (standard care) condition. If the participant agreed, an informed consent was obtained from her prior to the beginning of the study. Part of the informed consent process was to obtain permission from the participants to audio tape record each session and video tape some sessions in order to conduct quality checks and make sure that the outline was adhered to for each session. Baseline data was obtained prior to randomization to either the experimental or control condition. Ms. Hernandez remained blind as to which group each woman belonged so as not to influence the interview process.

Prior to the beginning of each intervention group (five in the first year), twenty women were randomly selected from the pool of available participants (total of 103 for the first five groups). The assessment instrument was mailed to these twenty participants and a time set for the baseline assessment telephone interview (T1). After the baseline assessment women were randomized to either the experimental and control condition. When the six session intervention group ended (T2), the assessment instrument was mailed to all participants and a telephone time set for the post-intervention interviews. A stamped, self-addressed envelope was mailed to the participant with the assessment instrument. Once the telephone interview was finished, the participant mailed the interview back so we could have a hard copy of the data.

Several measures were chosen to assess cognitive, psychological, and behavioral variables. The majority of these measures consist of structured questions and require about 30 minutes to complete. One of the Quality of Life measures, the Patient-Centered Methods, is semi-structured and takes about 20 minutes during the telephone interview, which is done after recording the responses to the structured measures. These measures are assessed at four points in time: T1 – baseline (prior to randomization); T2 – within one week after the six week intervention has ended; T3 – six months after the beginning of the intervention; and T4 – one year after the beginning of the intervention. The measures are listed below.

Measures used

Mammogram adherence
Clinical breast examination (CBE)
Breast self-examination (BSE)
Revised Rand General Well-Being Scale
Social Adjustment Scale-Self Report
Patient Satisfaction Subscales
Life Satisfaction Index
Patient-Centered Methods
Knowledge about Breast Cancer and Breast Cancer Screening
Breast Cancer Beliefs
Cancer Attitude Scales (Anxiety, Hopelessness, and Adjustment)
Coping Strategies
Sociodemographic information
Stressful Life Events
Risk status

b. Work to date as related to goals

1. In the Statement of Work (Appendix A) the five items in Task 1 have been accomplished. They are as follows.

a) All the materials to be used with those subjects in the experimental condition were ordered and received. They have been used in each of the five experimental groups conducted and will be ordered and used for each year.

b) All questionnaires to be used in this study were completed and sent to the Department of the Army. Other paperwork, such as labels being generated, envelopes addressed, and questionnaires copied for distribution to subjects, was also completed.

c) The Quality of Life measures were finalized and included in the interview packet for subjects.

d) The psychoeducational intervention manual was completed. It is currently being polished and placed into a bound format. Once this is finished it will be sent to the Department of the Army.

e) The research assistant and the research fellow were both trained on how to carry out their various responsibilities, which included, but was not limited to, patient contacts, interviewing subjects, and coding and entering data. The social worker initially hired resigned after five months as she had a physical injury that required treatment in another state. Subsequently we sought and obtained permission from the Department of the Army to hire another social worker as a consultant to carry out the rest of the four year study. To date, this social worker has conducted all five intervention groups.

2. In the Statement of Work the first item in Task 2 as been completed on schedule. Specifically, 170 women were contacted and asked to participate in the study. As anticipated 101 women agreed to participate in the study.

3. In the Statement of Work all the items in Task 3 have been completed (or are ongoing) as scheduled.

- a) After the initial interview, women were randomized to either the control (N=51) or experimental condition (N=50). Because we hired a new social worker to conduct the groups, they did not begin until the fifth month. Despite this initial delay we have completed five groups as initially planned. The number of women who completed the control condition was 45 and the number who completed the experimental condition was 38. In the control condition, one woman was diagnosed with breast cancer after completing the first questionnaire and therefore withdrew from the study. The other five women in the control condition withdrew from the study because they did not want to complete any more questionnaires. In the experimental condition, 12 women did not continue after randomization or withdrew from the study: 1) one woman did not have a family history of breast cancer (unknown to us until randomized); 2) two women never showed up; 3) one woman had to postpone starting until January 1996 because of back surgery; 4) one woman had to postpone starting until January 1996 because of job commitments; 5) two women were unable to complete all the sessions related to outside issues; 6) one woman had breast cancer (unknown to us until randomized); and 7) the other four women withdrew after randomization and prior to the beginning of the groups.
- b) The six month assessment has been completed for the first support group.
- c) Data entry began in the seventh month.

4. In the Statement of Work all the items in Task 4 have been completed (or are ongoing) as scheduled.

- a) All five groups were completed in the first year as planned.
- b) The six month "booster" session was conducted for the first group.
- c) Dr. Paul Jacobsen, a consultant in behavioral medicine, has conducted quality checks on the consistency and accuracy of the content of the sessions by listening to the audio cassettes.

5. In the Statement of Work all the items in Task 5 have not begun and are not scheduled until month 44.

VII. CONCLUSIONS

This study as designed is being carried out according to the Statement of Work. This research project will take a total of four years to complete and will be examining effects over time. The number of women participating in the first year of this study is small. Since preliminary data analyses has not been conducted, it is too early to report any findings or draw any meaningful conclusions. Anecdotal reports from women in the experimental condition indicate that they have obtained a tremendous amount of knowledge and feel less anxious about carrying out early detection behaviors for breast cancer.

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APPENDIX A

PSYCHOEDUCATIONAL GROUP INTERVENTION FOR WOMEN AT INCREASED RISK FOR BREAST CANCER

Task 1. Preparation of materials, intervention manual & training of staff– Months 1-3:

- a. Materials to be used with experimental condition will be ordered.
- b. Questionnaires copied, labels created, and envelopes addressed.
- c. Quality of life measures are finalized.
- d. The psychoeducational intervention manual will be completed.
- e. The research assistant, research fellow, and the social worker will be trained in their various responsibilities.

Task 2. Randomization of sample and recruitment of participants– Months 3-36

- a. Eligible women will be randomly sampled and recruited for participation. Recruitment for participation in this study will be done at one year intervals so that all the recruitment will not be done in the first year. In the first wave we will contact 170 women for the first year as we anticipate a 60% response rate and a need for 100 women.
- b. Second wave of recruitment begins (month 12), 200 women will be contacted to insure that we have 120 women for study.
- c. Third wave of recruitment begins (month 24), 200 women will be contacted to insure that we have 120 women for study.
- d. Fourth wave of recruitment begins (month 36), 34 women will be contacted to insure that we have 20 for study.

Task 3. Assessments collected– Months 3-48:

- a. Baseline assessments are collected prior to randomization to experimental (N=180) or control (N=180) condition for a total of eighteen cycles (N=360), with new intervention groups (experimental condition) starting every two months beginning in the third month (months 3-36).
- b. Six week, six month and one year assessments are collected on those in the experimental (intervention group) and control conditions.
- c. Data entry begins in month 5.

Task 4. Intervention groups and “booster” sessions conducted– Months 3-48:

- a. An intervention group (experimental condition) begins every two months, starting in month 3 (5 in the first year, 6 in the second year, 6 in the third year, and 1 in the fourth year).
- b. Six month and one year “booster” sessions are conducted for those in the experimental condition.
- c. Quality checks on consistency and accuracy of content of sessions are performed through the use of audio and video tapes.

Task 5. Data analyses– Months 44-48:

- a. Preliminary data analyses are begun in month 44.
- b. Tests of differences between experimental and control conditions on several variables (e.g., age, referral source, prior screening behavior, psychological distress) are begun in month 44.
- c. MANOVA and MANCOVA with repeated measures are performed starting in month 44.
- d. Final analyses are completed in month 48.

APPENDIX B

Psychological Counseling Strategies for Women at Risk of Breast Cancer

Kathryn M. Kash, Jimmie C. Holland, Michael P. Osborne,
Daniel G. Miller*

Women with family histories of breast cancer have a much higher risk of developing the disease than women in the general population. In the absence of primary prevention for breast cancer, secondary prevention in the form of early detection is our best bet against premature morbidity and mortality. This article describes the most salient psychological issues for high-risk women as well as ways for improving screening behaviors. Based on our work and other studies in the literature, we found that there were several key variables related to psychological distress and surveillance behaviors. Barriers to screening were a major reason why women did not engage in any breast cancer prevention behaviors. Cognitive deficits, in terms of lack of knowledge, and breast cancer misbeliefs contributed to poor adherence to screening. Most important, anxiety or emotional distress not only interfered with adherence to screening but also affected quality of life negatively in that many women needed psychological counseling. In developing psychological counseling strategies for high-risk women, we focused on the treatment outcomes of reducing emotional distress, decreasing perceived vulnerability, and improving adherence to screening behaviors. We conducted a preliminary study by piloting a group psychoeducational intervention for 6 consecutive weeks. This intervention was found to significantly reduce perception of risk ($P < .02$) and to increase adherence to screening behaviors ($P < .01$). If proven effective in a randomized controlled trial, this intervention can be proposed to other cancer centers and prevention programs for implementation and enhancement of the behaviors among high-risk women that will assure early detection and decrease breast cancer mortality. [Monogr Natl Cancer Inst 17:73-79, 1995]

It is estimated that one of every eight women will develop breast cancer during her lifetime (1). The risk is not evenly distributed in the population and is two to three times higher in women who have a first-degree relative with breast cancer as compared with women who have a negative family history (2,3). There is also some evidence that for women with a first-degree relative with bilateral premenopausal breast cancer (2,4) or unilateral breast cancer under the age of 40 years (5,6), the risk is even greater.

Women at increased risk of breast cancer need modifications to their screening guidelines (7). One suggestion is that women

with a first-degree relative with premenopausal breast cancer should have mammograms and clinical breast examinations (CBEs) at an earlier age (e.g., aged 35 years) (8). There is a consensus among those in charge of high-risk surveillance programs in the United States (e.g., Memorial Sloan-Kettering Cancer Center and the Strang Cancer Prevention Center, New York, N.Y., The Johns Hopkins Oncology Center, Baltimore, Md., and the University of California at Los Angeles Breast Center, Calif.) that women with strong family histories of breast cancer have mammograms every year after the age of 40 years and CBEs every 4-6 months (9). While there is no primary prevention for breast cancer, secondary prevention in the form of early detection offers the best chance against premature mortality.

In this article, we identify who is at high risk for breast cancer because of genetic factors. The levels of psychological distress and important barriers to screening in these women are recounted. Most important, counseling strategies to ameliorate the negative psychological sequelae and to improve adherence to screening recommendations are described.

Definition of High Risk

Despite the evidence linking genes (BRCA1, in particular) with breast cancer, reliable risk information has not been provided to the target population, that is, those at increased breast cancer risk conferred by family histories. The primary consequence has been a failure to provide information regarding appropriate surveillance actions to meet the added risk (9). This gap in the information chain assumes even more importance with gene testing for cancer predisposition, which is now on the verge of clinical application. A knowledge of risk-assessment principles and tools is essential to enable identification of candidates appropriate for testing and to provide those at risk with realistic risk figures for decision making.

In the absence of gene testing for breast cancer in the clinical setting, there needs to be a method of identifying women who are most likely to be at increased genetic risk. Two recent risk

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See "Notes" section following "References."

assessment systems derived by Gail et al. (10) and Claus et al. (11-13), have been accepted in establishing breast cancer risk. They differ from earlier systems because they are models based on large datasets rather than empiric analyses. The Gail model factors in epidemiologic risks (age at menarche, parity, and number of biopsies) and family history to arrive at relative and absolute risks based on the age of the consultand. It tends to underestimate risk due to family history because it only counts two first-degree relatives and does not recognize affected second-degree relatives as contributing to risk; affected paternal-line family members are also ignored. The Claus model is based solely on family history and age(s) at diagnosis of affected relative(s), with cumulative risks calculated for up to two affected relatives (first and/or second degree). The model assumes the existence of a rare dominant allele responsible for breast cancer predisposition. Neither the Gail nor the Claus model provides a fit for every positive history. The Gail model is useful when family history is not striking and other risk factors are present. Its most notable application has been in determining eligibility for the National Surgical Adjuvant Breast and Bowel Project Breast Cancer Prevention Trial, in which 16 000 North American women have enrolled. This is a double-blind randomized study of the effectiveness of tamoxifen versus placebo in preventing breast cancer.

We used the Claus model for defining risk status and entry eligibility for the Strang Breast Surveillance Program. Women had to fall into one of four high-risk categories: 1) two or more first-degree relatives (mother, sister, and daughter) with breast cancer before the age of 60 years; 2) a first-degree relative with bilateral premenopausal breast cancer; 3) a mother and maternal grandmother with breast cancer before the age of 60 years; or 4) a first-degree relative with unilateral breast cancer before the age of 40 years. These criteria were selected to include women whose lifetime risk of developing breast cancer on the basis of their family histories was between 17% and 50% (13). For example, a 30-year-old woman whose 27-year-old sister, mother, and maternal grandmother (both she and her twin sister had bilateral breast cancer before age 50) as well as six other second-degree relatives were all affected with breast cancer may be the carrier of an autosomal dominant gene (Fig. 1).

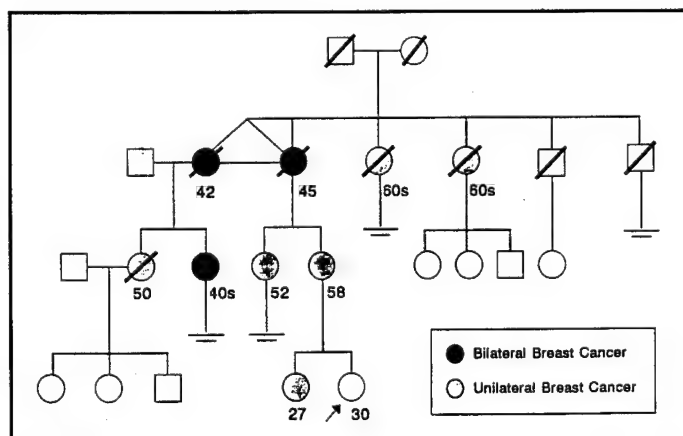


Fig. 1. Pedigree of a 30-year-old woman who sought risk counseling and screening recommendations.

Psychological Issues in High-Risk Women

Women who are at risk of developing breast cancer because of their strong family histories are also at higher risk for psychological distress (14-16). There are many issues for high-risk women who live with fear, anxiety, and uncertainty every day of their lives. The first and most overwhelming issue for women is their anxiety about developing breast cancer. Anxiety peaks at certain points in their lives, for example, when a woman reaches the age her mother or sister developed breast cancer. At that age, a woman becomes concerned that she too will develop breast cancer and die of the disease. Another peak in anxiety occurs when a woman has the same number of children as her mother did when she developed breast cancer. Some women magically believe that if they have fewer children, they will be protected against breast cancer.

A woman's sense of vulnerability leads to an overestimation of risk that in turn heightens her subjective certainty of developing breast cancer. Data from other studies (17,18) indicate that a substantial number of women with a family history of breast cancer have a heightened perception of risk. In particular, the study done in the United Kingdom, where one of 12 women is at risk, found that more than 45% overestimated their risk for breast cancer and only 11% correctly identified their risk. More than 80% of the 503 women in our study overestimated their risk of developing breast cancer, some by as much as four times greater than their actual risk. Fifteen percent of the women in our study provided an accurate perception of their risk and 5% underestimated their risk. Underestimation most frequently occurred when a woman had a very high risk (35%-50%) and had not received risk counseling. Frequently, women report that they are "100% sure" that they will get breast cancer, as well as describing themselves as "walking time bombs." In other words, women at genetic risk do not wonder *if* they will get breast cancer but rather *when* it will appear.

The fear of disfigurement or death is a common theme and is sometimes worse for women who were young when their grandmothers, mothers, and sisters developed the disease and died. Fears, such as having mutilating surgery for breast cancer, which may be irrational, are prevalent in their thinking. Many women remember the radical Halstead mastectomies of 20 years ago and believe this type of surgery will be performed on them if they develop breast cancer.

Variations in guilt are pervasive in women at high risk. Some women feel guilty because they were not there either physically or emotionally for their relatives who had had breast cancer. Other women feel guilty because they may have passed a gene to their daughters. Many women feel guilty because they are so worried and concerned about breast cancer and yet they are healthy. Women who have not developed breast cancer while other relatives have the disease feel "survivor" guilt.

The misconceptions and myths about breast cancer are overwhelming for many women. Some of these have been passed from one generation to the next. One myth is, "If you get hit in the breast, you will develop breast cancer." A misconception about breast cancer is, "If you have fibrocystic breasts, this leads to breast cancer." Yet another misconception is, "If you have surgery for breast cancer, it spreads."

Frequently, women who have strong family histories of breast cancer feel powerless about the disease. Women think they have a gene, they cannot control it, and breast cancer is their destiny. In addition, they felt helpless when their mothers and sisters had breast cancer and feel hopeless about avoiding the disease themselves. In other words, a woman's sense of self-efficacy regarding the prevention of breast cancer is lacking.

Another psychological issue for women at high risk is their passivity and their use of denial regarding breast cancer and, in particular, adherence to screening. Women frequently make statements, such as, "If I don't think about breast cancer, I can't get it" or "I just don't want to know if I have breast cancer." Sometimes, women join a surveillance program and after having a couple of negative mammograms and CBEs, they feel protected and postpone their future screening dates.

Finally, one of the major issues surrounding all of the above concerns is that women feel isolated and alone. Women stated that their surviving relatives are reluctant to discuss breast cancer with them. Generally, these women feel that no one else knows how they are feeling. Their friends are not interested in discussing their "obsession" with breast cancer.

Studies have found that levels of psychological distress, such as greater cancer anxiety (14), more intrusive thoughts (15), and higher perceived susceptibility (16), were associated with a decrease in mammograms, CBEs, and breast self-examinations (BSEs). In our study, we found that levels of psychological distress, as measured by the Global Severity Index of the Brief Symptom Inventory (19), in high-risk women were one half to one standard deviation above the mean for normal women in the population. More than 28% of high-risk women were defined as having a level of psychological distress consistent with the need for counseling. One of our most striking findings was that high-risk women's scores were similar to those of women who were survivors of Hodgkin's disease and leukemia (Fig. 2). These high levels of distress diminished their quality of life. Many

women thought about breast cancer every day of their lives, postponed marriage, and decided not to have children because they were 100% certain they would develop breast cancer and die of the disease.

Screening Adherence

In our study of 503 women at high risk attending a surveillance program, we found lower rates of screening adherence in women who were more distressed. While 52% came in for regular CBEs, only 27% performed BSEs monthly. In women over the age of 40 years, less than one half (46%) came in for yearly mammograms. For all three methods of early detection, greater cancer anxiety and psychological distress were significant predictors of poor adherence. We also found that younger, well-educated women were less likely to perform a monthly BSE ($P < .01$). A multiple regression analysis revealed that women with the highest psychological distress levels had more barriers to screening as well as an interaction effect of low social support and more barriers (Table 1).

Barriers to Screening

Studies (20) have found that the major barriers to mammography are lack of physician recommendation or referral and the cost of having one. However, women who participate in the Strang Breast Surveillance Program are physician or self-referred and mammograms and CBEs are done at a low cost to the patient. While these major barriers have been eliminated for women in the Surveillance Program, other barriers impact on women having mammograms and CBEs and performing monthly BSEs.

Overestimation of risk is a major barrier to screening. The higher a woman's perception of risk, the less she adheres to regular mammograms and CBEs and the less she performs monthly BSEs. Often, the fear of finding a lump represents a

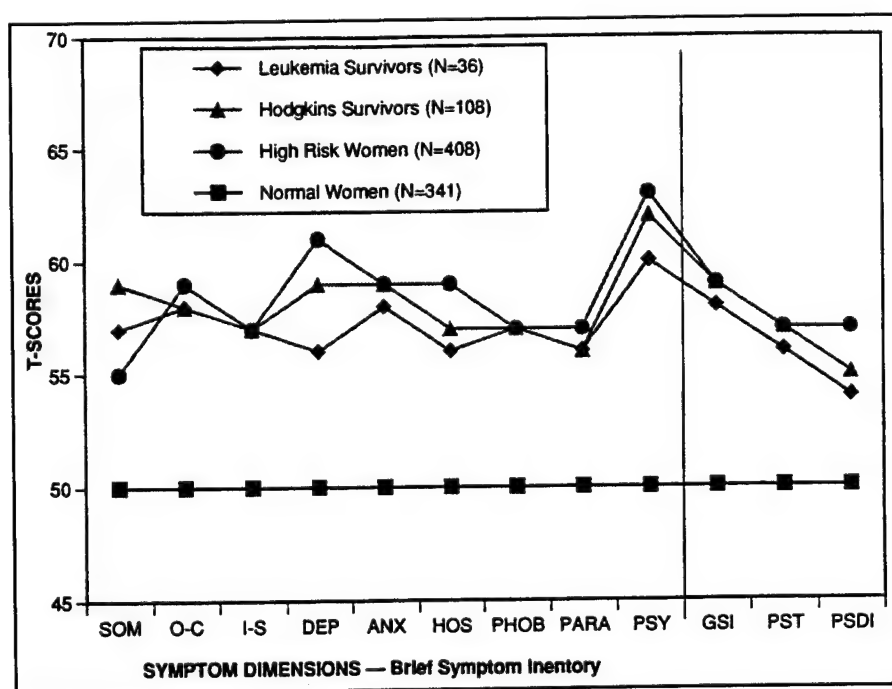


Fig. 2. Psychological distress scores of normal and high-risk women as compared with women who had Hodgkin's disease and leukemia. SOM = somatization; O-C = obsessive-compulsive; I-S = interpersonal sensitivity; DEP = depression; ANX = anxiety; HOS = hostility; PHOB = phobic anxiety; PARA = paranoid ideation; PSY = psychoticism; GSI = Global Severity Index; PST = positive symptom total; PSDI = positive symptom distress index.

Table 1. Factors predicting psychologic distress (n = 420)

	Beta*	P
Perceived barriers	.83	.0001
Barriers and social support (low social support and many barriers)	-.72	.0001
Social desirability (denial of undesirable qualities)	-.31	.0019
Perceived risk	.12	.0288

*Multiple $R = .68$.

barrier. As the time gets closer for a woman to have a mammogram or CBE or perform BSE, her anxiety about what might be found increases. The intense fear associated with losing a breast through a mastectomy results in women postponing their appointments for screening. Frequently, women will avoid screening as a way of handling their fears.

Sometimes women are concerned about the levels of radiation they are exposed to during a mammogram. One woman believed that one more mammogram view would be her downfall and she would get breast cancer from it. Another barrier to screening adherence is the amount of physical discomfort from having a mammogram. Most women describe having a mammogram as uncomfortable. However, some report that it is extremely painful and this deters them from obtaining future mammograms.

In some families, cancer was a taboo subject (since it was frequently equated with a death sentence) and breast cancer was a secret for many years. Female sexuality is frequently associated with breasts by both men and women. Consequently, some women regard their breasts as desirable for intimate pleasure. This results in women feeling embarrassed about having their breasts examined by a physician or nurse practitioner or embarrassed about examining their own breasts.

Over one third of the women in our program report that coming to the clinic for an examination, whether it is a mammogram or CBE, is emotionally distressing. A clinic visit is a reminder of experiences with relatives and friends with breast cancer and evokes a multitude of responses in women. Some women become tearful when they walk in the door and others avoid screening as a way of circumventing the emotional upheaval. Taking time from other activities was also a barrier to screening for more than 50% of the women. It is evident that some women prefer doing anything rather than adhering to screening recommendations.

Improving Surveillance Behaviors

From the data above, it became clear that we had to find ways to ameliorate the negative psychological sequelae and to help women at high risk of breast cancer adhere to all three methods of screening. For most of the population, the cost of mammograms and physician recommendations are extremely important. Low cost, good-quality mammography clinics should be established for those who cannot afford the high cost privately. Also, perhaps the physician should make a mammogram appointment for women, rather than leaving it up to their discretion.

One way to improve screening adherence is to enhance the role of professionals. Physicians need to refer their patients for breast cancer screening on a timely basis. Primary-care clinicians should be developing protocols for risk assessment and work within the context of breast surveillance programs. One component of the assessment would be the genetic-risk assessment done by the genetic counselor or a health professional trained in this field. The manner in which risk information is provided to high-risk women is a crucial variable in the psychological distress and screening adherence equation. For example, if a woman has a 40% lifetime risk of developing breast cancer, this information can be presented to her by conveying the message that her chance of not developing breast cancer is 60%. Also, the risk counselor should advise her regarding the risk for 10-year intervals, as well as how much risk has already been expended during her life (10,21). This positive communication, coupled with screening recommendations tailored specifically to the woman, may help to provide reassurance regarding a longer life span and may reduce emotional distress.

Since barriers to screening resulted in psychological distress and decreased adherence, ways to diminish the barriers that interfere most with screening behaviors must be identified. Another method of increasing surveillance behaviors is to expand women's knowledge about early detection and breast cancer. Many women still equate breast cancer with death, and they lack state-of-the-art information regarding low-dose radiation from mammography, breast-conserving surgery, and a 92% cure rate with the early detection of breast cancer.

Another aspect of improving screening adherence revolves around reinforcement and reminders of specific behaviors. Women need to be taught how to do a BSE properly, need to be given a return demonstration at each clinic visit, and need to be provided with reinforcement by the physician or nurse practitioner. Handing out stickers for women to put on their calendars is an effective reminder to perform monthly BSEs. Surely, sending reminder cards a month or two before a date for a mammogram or a CBE will facilitate attention to these important endeavors.

Psychological Counseling

Psychological counseling for a woman who has a family history of breast cancer is extremely important and varies from woman to woman. The potential results of counseling include the following: 1) reduction of emotional distress and anxiety, 2) decrease in perceived vulnerability, 3) change in health beliefs (changing the barrier/benefit screening ratio), and 4) improvement in adherence to screening behaviors. These treatment outcomes follow from what women have defined as the most salient issues, and are a realistic way of improving women's quality of life.

Individual Treatment

Frequently, women who seek individual counseling are those who are primarily concerned with the impending or recent death of their mother or sister. They are seeking psychological support in order to cope, both physically and emotionally, with their relatives' breast cancer. Sometimes women need permission to

take time for themselves and not focus all their energy on being a caretaker. Yet others look for a place in which they can describe all that they are doing for their relative. Women's intrusive thoughts about breast cancer occur on a daily basis, frequently interfere with daily activities, and may continue for years after the death of a relative.

Other women undertake individual counseling because they feel they have no place to turn and they lack the necessary social supports for dealing with their breast cancer risk. Not surprisingly, risk information is repeated many times for women who need to hear their objective medical risk over and over again, as it is incongruent with their perception of risk. Descriptions of a deceased relative in terms of physical appearance, accomplishments, or other attributes may persist for a long period of time. Frequently, this is a necessary component of the healing process. Women's own fears of death and dying are foremost in their minds, most often around the time of an examination for breast cancer.

Psychoeducational Group Intervention

On the basis of our findings from the study mentioned above, we began to investigate ways to decrease the emotional distress of high-risk women, to help them cope actively, and to adhere to early-detection procedures. Because high-risk women increasingly identify themselves and look for programs where they cannot only find appropriate surveillance guidelines but also share their feelings and concerns with others, the efficacy of a group intervention needed exploration. We conducted preliminary studies by piloting a group psychoeducational intervention, based on a self-regulation theory (22,23). This theory was developed by researchers to explain how people cope with stressful situations or how people adapt to health threats.

There were three important components to this 6-week structured intervention. The first was educating women by the following methods: 1) providing them with objective risk status (using the Claus model described above) based on their family tree (pedigree); 2) clarifying information about breast cancer and other risk factors for breast cancer; 3) providing information on ways to take control of their lifestyle by changing their eating patterns; 4) providing instructions on BSE using both active and passive methods; and 5) reinforcing the importance of adherence to screening guidelines. The second component revolved around cognitive restructuring, which helps to facilitate problem solving. That is, we encouraged women to use active coping rather than avoidance or denial in dealing with their risk status. In addition, changing cognitions can help to alleviate anxiety and the sense of helplessness. The last component was that of emotional support that helped to: 1) decrease the sense of isolation, 2) encourage the sharing of feelings and thoughts with others, and 3) provide reassurance by and rapport with other women. After 6 weeks, we were able to decrease perception of risk so it corresponded to accurate genetic risk, correct misconceptions about breast cancer, and increase adherence to screening procedures.

Women were randomly selected and assigned to either the experimental or control condition and assessed for demographic, psychological, social, and risk variables before and after the intervention took place. The interviewer was blind as to which

condition the woman was assigned. There were 10 women in each of the conditions for both the pilot and preliminary studies.

Within the experimental condition there was a significant increase in knowledge ($P < .05$), a significant decrease in perceived risk or susceptibility ($P < .015$), and a significant decrease in perceived barriers to screening ($P < .05$) between base line and 6 weeks (the end of the intervention). Analyses of variances at 6 weeks revealed several changes between the conditions: 1) a significant increase ($P < .005$) on knowledge of breast cancer in the experimental group, 2) a significant decrease ($P < .02$) on perceived barriers in the experimental group, and 3) a significant increase ($P < .03$) on knowledge of the risk factors for breast cancer in the experimental group. For example, at the end of 6 weeks, there were still women in the control condition (30%) who thought that being "hit in the breast" increased one's chances of developing breast cancer.

Because women overestimate their risk, we examined differences between groups and within groups on their objective medical risk and their perception of risk across time. Prior to the group intervention, there was a significant difference between women's perception of their risk (mean perception score, 51%-60%) and their objective risk status (mean objective risk, 31%-40%). This was true for both the experimental ($P < .01$) and control ($P < .003$) conditions. There was no difference between the conditions on perception of risk. At the end of the preliminary trial, there was a significant decrease ($P < .01$) on the perception of risk in the experimental condition, but not the control condition. There was no significant difference in the experimental condition between their perception of risk and objective risk status after the trial ended. However, there continued to be a significant difference between perception of risk and objective risk status (Fig. 3) for the control condition ($P < .02$). All women are provided risk counseling when they enter the program. Thus, it appears that when given a pedigree in a small group setting and a careful explanation of their risk, women who came to the group sessions were able to assimilate this objective information into a scheme and decrease their subjective overestimation of risk. However, the women in the control group ($n = 20$) were worrisome in that their perception of risk continued to increase over time. If we find that this overestimation within the control group continues in our large, randomized controlled trial, we will need to identify ways to intervene with these women.

One of the essential features of these psychoeducational groups is a booster session. The purpose of these sessions is a follow-up to the intervention to provide women with an opportunity to meet again as a group and talk about the ways in which they have used the information to help change their cognitions and adapt their coping skills in everyday life. One of the major components influencing the content of the intervention is social support enhancement. These booster sessions provided such a forum for women to obtain this support. Women were also encouraged to talk about the changes in their fears and worries about breast cancer and their life goals. Over the past 3 years, we have had such sessions for our first pilot group. Adherence to screening was significantly improved ($P < .01$) and has been sustained in the years since the initial group was conducted (Fig. 4).

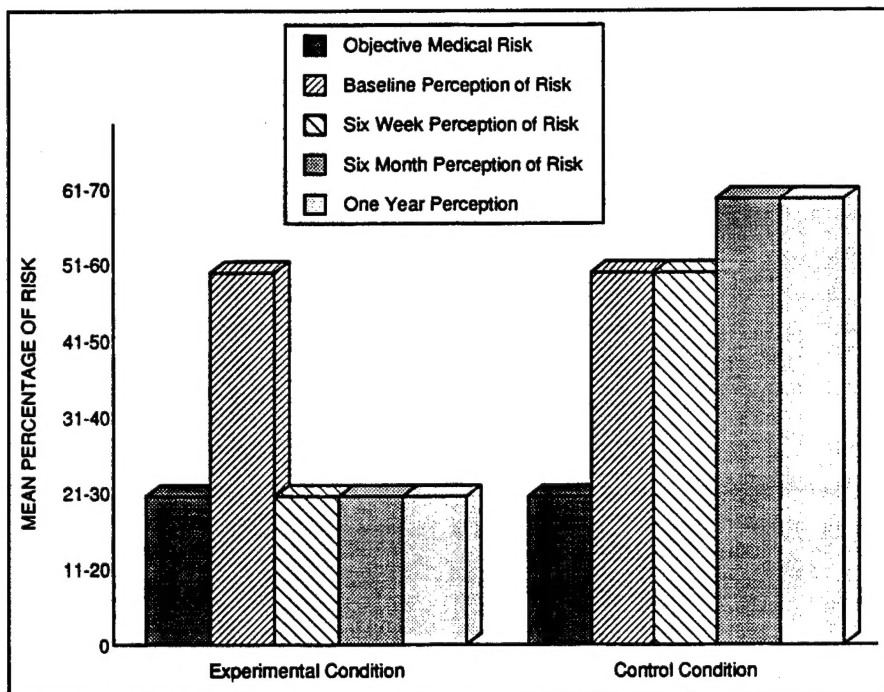


Fig. 3. Comparison of experimental and control conditions on medical risk and perception of risk at base line, 6 weeks, 6 months, and 1 year. Significant difference between experimental and control conditions at 6 weeks, 6 months, and 1 year ($P < .02$).

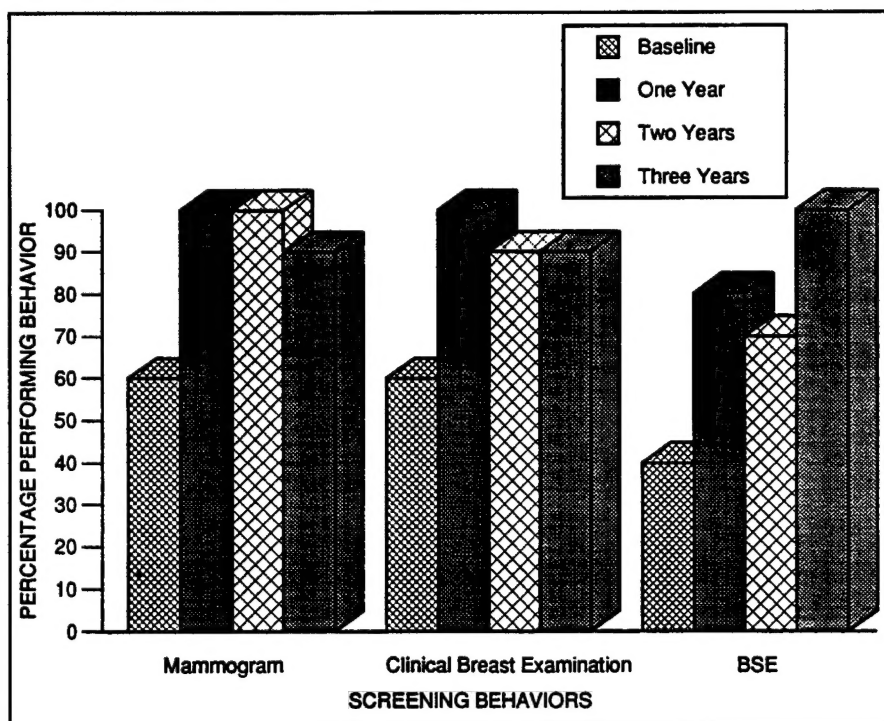


Fig. 4. Percentages of women at high risk of breast cancer adhering to mammogram, CBE, and BSE prior to support group, 1, 2, and 3 years postintervention ($P < .01$).

Conclusion

Women with family histories of breast cancer are at two to three times greater risk of developing breast cancer compared with those who have a negative family history. As women learn about their family histories, they begin to speculate about their own risks. Without adequate information, many women overestimate their risk and become quite fearful that they too could develop breast cancer. We felt compelled to investigate the psychological impact that being at high risk had on these

women. The most intriguing findings from our study were 1) anxiety interfered with adherence to mammogram, CBE, and BSE, and 2) levels of psychological distress equaled those of women who were survivors of Hodgkin's disease and leukemia. This research led us to focus on psychological counseling strategies, particularly group interventions, which may help women cope with being at genetic risk of breast cancer. From these groups, we were able to help women estimate their risk accurately, increase their knowledge of breast cancer, and improve their adherence to screening behaviors. We are presently con-

ducting a large, randomized trial investigating this treatment modality.

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Notes

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